FDA approves Biogen's oral MS drug, Tecfidera

WASHINGTON | BY TONI CLARKE

A pedestrian passes the sign outside the headquarters of Biogen Idec Inc. in Cambridge, Massachusetts June 18, 2008. REUTERS/BRIAN SNYDER

U.S. regulators on Wednesday approved a new multiple sclerosis drug made by Biogen Idec Inc that is widely expected to become the No. 1 oral treatment for the disease, with annual sales topping $3 billion.

The drug, Tecfidera, activates a chemical pathway in the body known as Nrf2 that helps protect nerve cells from damage and inflammation. Following Wednesday's approval by the Food and Drug Administration, Biogen said it will launch the drug within the coming days.

Multiple sclerosis is a chronic condition that attacks the central nervous system and can lead to numbness, weakness, paralysis and blindness. It affects more than 2.1 million people worldwide, according to the National Multiple Sclerosis Society.

"We expect a solid launch of Tecfidera, and our sense is that there is a bolus of patients in the queue ready to transition to therapy," Geoff Meacham, an analyst at J.P. Morgan, said in a research note. "However, we believe that Street expectations likely already account for this and then some."

Shares of Weston, Massachusetts-based Biogen rose 3.2 percent to close at $182.68 on Wednesday. The shares have more than tripled over the past three years, mainly driven by high hopes for Tecfidera, known chemically as dimethyl fumarate.

Biogen already sells the MS drugs Avonex and Tysabri, which together account for about 30 percent of the market. Teva Pharmaceutical Industries Ltd's drug Copaxone is the current market leader, with a roughly 29 percent share and annual sales last year of more than $4 billion.

Unlike Copaxone, Avonex and Tysabri, which are injected or infused, Tecfidera comes in the more convenient form of a pill. As such, it will compete with Novartis AG's MS pill Gilenya, which, though first to market, has been dogged by heart safety concerns. Gilenya holds an 8.5 percent share of the market and generated worldwide sales of $1.2 billion last year.

Tecfidera will also compete with Sanofi's recently approved MS pill Aubagio. Aubagio's label carries a boxed warning -- the most serious kind of warning -- alerting physicians to a potentially heightened risk of liver problems.

Novartis said in a statement that it welcomed additional treatment options for people with MS, but warned that Tecfidera may not perform as well in the market as in clinical trials.

"As with any new medication, real-world experience is critical to gain an accurate understanding of a therapy's full clinical profile," the company said. "It will be important to see the clinical profile of dimethyl fumarate -- including efficacy, safety, tolerability and adherence with its twice-a-day dosing -- as it gains real-world experience."

Michael Yee, an analyst at RBC Capital Markets, said the overall profile of Tecfidera looks "significantly better than Gilenya."

Tecfidera's side effects appear relatively benign, consisting mainly of flushing, diarrhea and nausea. And its label contains no boxed warnings. The FDA recommended only that physicians monitor patients' infection-fighting white blood cell count once a year.

"That's an excellent label," said Yee. "I expect the drug to meet consensus of $300 million this year, and over five years it can achieve greater than $3 billion in sales based on its convenience and efficacy profile."

Tecfidera will be used to treat patients with relapsing-remitting MS, a form of the disease in which flare-ups are followed by periods of remission. About 85 percent of people with MS are initially diagnosed with this form of the disease.

Combined clinical trial data showed Tecfidera cut the average relapse rate by 49 percent after two years compared to patients taking a placebo. The drug is expected to generate sales of about $3 billion in 2017, according to data compiled by Thomson Reuters Cortellis.

Last week European regulators recommended approval for Tecfidera and Aubagio, but they declined to give Aubagio a "new active substance" designation because it is similar to an older drug. Without this designation, generic copies of the drug could be launched in Europe in as little as three years. That could hurt sales of most other MS drugs on the market.

Sanofi said it was disappointed by the decision and plans to request a re-examination of the case.

(Reporting By Toni Clarke in Washington; additional reporting by Bill Berkrot in New York; Editing by Tim Dobbyn, Bernard Orr and Leslie Adler)